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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,531	07/28/2000	Stephen A. Berry	ARC2914C1	3299

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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10/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/627,531	Applicant(s) BERRY ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17,18,20,21,23-27,29-31,33-41 and 49-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17,18,20,21,23-27,29-31,33-41 and 49-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of request of power of attorney, amendment and remarks, all filed 08/02/07. Claims 52 and 53 are canceled. Claims 17, 18, 20, 21, 23-27, 29-31, 33-41 and 49-51 are pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 17, 18, 20, 21, 23-27, 30, 31, 33-36, 38, 40, 41 and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US 5,882,676 provided by applicants on Form PTO 1449) in view of Gyory (US 5,668,170)

Lee et al. (US 5,882,676 provided by applicants on Form PTO 1449) discloses compositions comprising testosterone, lauryl lactate, lactic acid, glycerol monolaurate, DEA and EVA (Table 1). Testosterone is a hormone, meeting the hormone limitation of the beneficial agent in the claims. DEA and EVA meet the limitation of polymer in claims 17, 16 and 33. Lee's composition enhances the permeation of active agents through the skin and is topically administered.

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Gyory discloses compositions that are delivered through the body surface in the presence of electrotransport enhancers (abstract); lauryl lactate and polysorbate and PEG-4 dilaurate are listed as electrotransport enhancers (Table 1 and column 14, lines 53, 63 and 64); testosterone, tetracaine, peptides and proteins are few of the beneficial agents that are deliverable with the electrotransport delivery device of Gyory (column 7, lines 18, 20 and 25-52).

Polyvinylpyrrolidone is preferred polymer that is blended with the beneficial agent in any ratio (column 10, lines 32-35 and 56). Testosterone is a hormone that meets the limitation of the claimed beneficial agent. Regarding the sterile nature of the biocompatible vehicle, it is noted that, it would be obvious for the implant to be sterile since sterilization frees the product from pyrogens that may do harm to the biological system if implanted or injected without sterilization. Regarding the physical stability of the formulation at body temperature for at least a month represents what would happen to the formulation at or after implantation or injection. The formulation of Lee in view of Gyory would undergo the same physical stability at or after implantation.

The composition of Lee enhances the transport of beneficial agents through the skin. The composition of Gyory enhances the transport of beneficial agents through the skin.

Lee discloses composition containing testosterone, lauryl lactate, lactic acid, glycerol monolaurate, DEA and EVA. The composition of Lee does not contain surfactant. However, Gyory discloses a delivery vehicle that contains polymer, lauryl lactate and surfactant such as polysorbate. Regarding the selection of solvent and surfactant and polymer for a formulation that would exhibit viscosity that is capable of suspending the beneficial agent, it is noted that the skilled artisan or the person of ordinary skill is technically able, using the general teaching of

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Lee and/or Gyory, to formulate a composition that would be able to suspend the beneficial agent. Regarding claim 25, 26 and 31, stability of the formulation for the designated time is a property/characteristic of the formulation and a formulation/product cannot have mutually exclusive properties. Adaptation of a formulation for use in an implantable device as in claim 27 is an intended use/route of the composition, and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The limitation of claims 50-53 is met by the presence of glycerol monolaurate in Lee and polysorbate surfactant in Gyory. Regarding the recited amounts of active agent, Gyory discloses that the active agent is blended with the polymer in any ratio and Lee discloses 10% testosterone meeting the limitation of the % amount recited in claims 20, 21, 34 and 35. However, there is also no demonstration in applicants' specification showing that the amounts recited for the beneficial agents provide unusual and unexpected results. It is within the purview of the skilled artisan or the ordinary skilled practitioner to use amounts of solvent and polymer adequate for the formulation. Regarding claims 40 and 41, it is within the purview of the ordinary or skilled artisan to determine duration of treatment or effective management of the condition being treated. The skilled artisan or the ordinary person in the art is able to determine how much solvent, surfactant and polymer to use as it regards to claim 49.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Lee to formulate a testosterone for enhanced topical delivery. One having ordinary skill in the art would have been motivated to combine the

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composition of Lee and Gyory to make a third formulation for the same purpose. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their having been individually taught in the prior art.” In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Response to Arguments

3. Applicant's arguments filed 08/02/07 have been fully considered but they are not persuasive.

Applicant argues that the combined teaching of Lee and Gyory does not teach non-aqueous single-phase biocompatible vehicle comprising a surfactant, a polymer and a solvent, where the solvent is lauryl lactate or lauryl alcohol, where the surfactant is selected from the group consisting of polyhydric alcohols, ethoxylated castor oil, polysorbates, esters or ethers of unsaturated alcohol and polyoxyethylenepolyoxypropylene block copolymers, and where the polymer is selected from the group consisting of polyesters, pyrrolidones, esters or ethers of unsaturated alcohols and polyoxyethylenepolyoxypropylene block copolymers as required by the claims.

Response

Lee and Gyory both teach compositions that contain lauryl lactate, which is one of the recited solvents; Gyory teaches composition that contains polysorbate, which is one of the recited surfactants and polyvinylpyrrolidone, which is a pyrrolidone and does meets the

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requirements for polymer and the combination of lauryl lactate, polysorbate and polyvinylpyrrolidone forms the non-aqueous single phase. None of the references describe the presence of aqueous phase with lauryl lactate, polysorbate and polyvinylpyrrolidone.

4. Claims 17, 29, 37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US 5,882,676 provided by applicants on Form PTO 1449) in view of Gyory (US 5,668,170) and further in view of Benson et al. (US 4,078,060).

The combined formulation/composition of Lee and Gyory is described above. However, the combined formulation/composition of Lee and Gyory does not include antioxidants. But Benson discloses that testosterone can be administered parenterally, by depot injection or implantation (column 3, lines 18-54; column 4, lines 53 and 54; column 5, lines 32, 46; column 10, lines 42 and 43; Table 1); the composition can also contain antioxidant (column 6, lines 3-10). Thus Benson shows that antioxidant can be included with testosterone. Regarding implantation and parenteral administration, it is known in the art that testosterone can be administered parenterally or by implantation as disclosed by Benson.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teachings of Lee and Gyory and add antioxidant as disclosed by Benson to protect the testosterone composition from oxidation.

Response to Arguments

5. Applicant's arguments filed 08/02/07 have been fully considered but they are not persuasive.

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Applicant argues that the combined teaching of Lee and Gyory does not teach non-aqueous single-phase biocompatible vehicle comprising a surfactant, a polymer and a solvent, where the solvent is lauryl lactate or lauryl alcohol, where the surfactant is selected from the group consisting of polyhydric alcohols, ethoxylated castor oil, polysorbates, esters or ethers of unsaturated alcohol and polyoxyethylenepolyoxypropylene block copolymers, and where the polymer is selected from the group consisting of polyesters, pyrrolidones, esters or ethers of unsaturated alcohols and polyoxyethylenepolyoxypropylene block copolymers as required by the claims; that Benson fails to remedy the deficiency of the Lee in view of the Gory reference.

Response:

Lee and Gyory both teach compositions that contain lauryl lactate, which is one of the recited solvents; Gyory teaches composition that contains polysorbate, which is one of the recited surfactants and polyvinylpyrrolidone, which is a pyrrolidone and does meets the requirements for polymer and the combination of lauryl lactate, polysorbate and polyvinylpyrrolidone forms the non-aqueous single phase. None of the references describe the presence of aqueous phase with lauryl lactate, polysorbate and polyvinylpyrrolidone. Benson, was not used to overcome the deficiencies of Lee and/or Gyory, rather, Benson is relied upon for a disclosure that antioxidant can be combined with testosterone.

Regarding parenteral administration of the claimed composition, it is noted that the formulation derived from the combined teachings of Lee and Gyory comprises lauryl lactate,

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surfactant and polymer and testosterone as the active agent and that the formulation comprising the testosterone can be administered topically. Benson suggests that testosterone can be administered parenterally. Thus, Benson is relied upon for suggesting parenterally administering testosterone-containing composition. Applicant has not provided factual showing that the testosterone containing formulation derived from the combined teaching of Lee and Gyory cannot be administered parenterally. Guidance/suggestion provided by Benson is that a testosterone containing composition is parenterally administrable.

NO claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

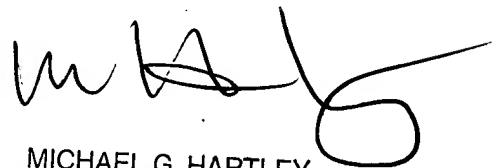
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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(BF)



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER